

## REMARKS

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the remarks herein.

### **I. STATUS OF THE CLAIMS AND FORMAL MATTERS**

Claims 1, 3-4, 6-17, 20-26, 28-32 and 35-40 and 42-43 are now pending. New claim 43 is added herein, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is submitted that these claims are and were in full compliance with the requirements of 35 U.S.C §112. In addition, the amendment and remarks herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§101, 102, 103 or 112; but rather the amendments and remarks herein are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Support for the amended claims is found throughout the specification.

### **II. THE ART REJECTIONS ARE OVERCOME**

Claims 1, 4, 6, 9-17, 20-26, 28-32 and 35-42 were previously rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Krieg *et al.* (U.S. Patent No. 6,339,068). The rejection is respectfully traversed.

The October 10, 2006 Advisory Action indicated that the March 9, 2006 Amendment would be entered, but that the amendment did not place the application in condition for allowance because the present claims recited that the skin is “contacted”, for which there is allegedly unclear metes and bounds thereby allegedly placing the claims within the scope of Krieg *et al.* Applicants respectfully disagree with the statements of the Advisory Action and maintain that the term “contacted” is defined by specific metes and bounds and is outside the scope of Krieg *et al.*

Applicants maintain that Krieg *et al.* clearly describes an invasive procedure where the skin is not “contacted” with plasmid DNA, but is pierced by particles coated with plasmid DNA. This distinction is evidenced by the language in Krieg *et al.* that states “[p]lasmid DNA may be coated onto gold particles and introduced biolistically with a ‘gene-gun’ into the epidermis if

[sic] the skin or the oral or vaginal mucosae". Column 10, lines 54-57. Accordingly, as is explicitly stated in Krieg et al., the use of a gene gun does not deliver the gene products onto the skin as is required by the present claims and as is meant by the term "contacted" when the term is read in accordance with the specification, but rather the gene gun deliver the gene products into the epidermis.

Indeed, the present specification consistently describes the administration of the vector onto the skin of the subject as the skin being "contacted" with the vector. Furthermore, the working examples provided in the application utilize vectors that were "pippetted" onto the skin of the animals, which is akin to the use of an eyedropper or other similar item to apply a liquid to the outermost surface of the skin, without causing the penetration of the skin. Clearly, such an application is consistent with the term "contacted" as used in the present invention.

The application additionally contains numerous references to the "contacting" of skin with the present invention by means of "topical application." For instance, Example 12 states that "adenovirus recombinants, DNA/adenovirus complexes, or DNA/liposome complexes were allowed to contact mouse skin by topical application" (specification at page 37, lines 14-15). The present invention is also described as a method comprising "contacting skin of an individual or animal in need of such treatment by topically applying to said skin an immunologically effective concentration of a genetic vector encoding a gene of interest" (specification at page 8, lines 19-21).

These examples are consistent with what one of skill in the art would consider a non-invasive administration comprising contacting the skin or topically applying to the skin the vectors of the present invention. One of skill in the art would simply not consider the use of a gene gun consistent with non-invasive administration, contacting the skin, or with topical application.

Furthermore, it is respectfully submitted that to require Applicants to amend the claims to alter the term "contacting" is prejudicial to Applicants and is not in accordance with the scope of the claims afforded Applicants in related applications.

Accordingly, the use of a gene gun is outside the scope of the present claims as the use of a gene gun is contrary to the claimed "non-invasive" immunization comprising "contacting" the skin when the claims are read in light of the specification and the metes and bounds afforded the term "contacting" therein. Therefore, as Krieg *et al.* only teaches the use of a gene gun, and does

not teach or suggest the non-invasive application of bacterial vectors to the skin, the rejection is improper and cannot stand. Reconsideration and withdrawal of the rejection under 35 U.S.C. §102(e) is respectfully requested.

**REQUEST FOR INTERVIEW**

If any issue remains as an impediment to allowance, prior to issuance of any paper other than a Notice of Allowance, an interview, is respectfully requested, with the Examiner his supervisor, and, the Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

**CONCLUSION**

In view of the amendments, and remarks herein, the application is in condition for allowance. Reconsideration and withdrawal of the rejections of the application, and prompt issuance of a Notice of Allowance, is respectfully requested.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP

By: *Thomas J. Kowalski by Angela M. Collison*  
Thomas J. Kowalski  
Reg. No. 32,147  
Angela M. Collison  
Reg. No. 51,107  
(212) 588-0800